REMARKS

Double Patenting

Claims 217-262 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over various claims of co-pending U.S. Patent Application No. 09/970,023. Since the obviousness-type double patenting rejection is provisional, the Applicant is currently not required to respond to the rejection.

Claim Rejections – 35 USC §102 and §103

Claims 230-239, 245-257 and 259-262 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,033,438 to Bianchi et al. Additionally, claims 217-229, 240-244 and 258 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,033,438 to Bianchi et al. in view of U.S. Patent No. 4,904,261 to Dove et al.

It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent Claim 217 and Dependent Claims 218-229, 240-244 and 263-270

Independent claim 217 has been rejected as being unpatentable over Bianchi et al. in view of Dove et al. and recites, among other elements and features, "an elongate bone portion formed from a cross-sectional bone slice taken from a diaphysis of a long bone having an outer cortical bone wall surrounding an inner medullary canal", a first sidewall including "a recessed area disposed between said first and second end portions, said recessed area defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface extending . . . between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and a second sidewall arranged generally opposite the first sidewall and including "a convex outer surface extending between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface of said first sidewall extends generally parallel with and is positioned opposite said convex outer surface of said second sidewall to

provide said elongate bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis".

The Office Action states that Bianchi "did not teach of a second sidewall including a convex surface extending along the longitudinal axis between the first and second portions". Nevertheless, the Office Action asserts that Dove "evidences the use of a spinal implant having a convex surface opposite the concave surface to increase the stability of the implant during use. Therefore, . . . it would have been obvious . . . to modify the device of Bianchi et al, as taught be Dove (sic) to increase the stability of the implant during use". (Page 6, lines 1-8). The Applicant respectfully disagrees with these assertions for at least the following reasons.

Although Dove discloses a spinal implant, Dove teaches that the implant is formed of bio-compatible materials including "carbon-fiber-reinforced plastics, such as epoxy resin", "an inert or bio-degradable fiber-reinforced composite, or calcium nitride", or "metals such as titanium . . . and stainless steel, or ceramics, polyethylene hydroxyapatite and poluetylene hydroxybutyrate". (Column 1, lines 46-53; column 2, lines 8-9). Although Dove discloses a laundry list of materials from which the implant may be fabricated, there is absolutely no teaching or suggestion whatsoever of forming the implant from "an elongate bone portion formed from a cross-sectional bone slice taken from a diaphysis of a long bone having an outer cortical bone wall surrounding an inner medullary canal", nor is there any teaching or suggestion that the gap region 16 of the implant is "defined by a partial portion of the medullary canal of the long bone", as recited in independent claim 217. Instead, Dove specifically discloses that the implant is formed from man-made materials, and not from bone. Accordingly, there would be no motivation for one of ordinary skill in the art to combine the features associated with the Dove implant with the Bianchi implant to arrive at the invention recited in independent claim 217.

Furthermore, the Applicant submits that according to the Examiner's statements, Bianchi does not disclose an implant including "a first sidewall . . . including a recessed area . . . between said . . . end portions, said recessed area defined by a partial portion of the medullary canal . . . and defining a concave outer surface . . . and a second sidewall . . . including a convex outer surface . . . and wherein said concave outer surface . . . and . . . said

convex outer surface . . . with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis". As indicated above, the Office Action states that Bianchi "did not teach of a second sidewall including a convex surface extending along the longitudinal axis between the first and second portions".

Assuming arguendo that the Dove implant includes outer concave and convex surfaces, the Dove implant is not provided with "an elongate crescent-shaped outer cross-section". Instead, the Dove implant is repeatedly described throughout the specification as having a "horseshoe" shape. Additionally, as shown in Figures 1 and 2, the horseshoe-shaped implant has an annular configuration which extends beyond 180 angular degrees. The Applicant submits that the horseshoe-shaped implant of Dove does not have "an elongate crescent-shaped outer cross-section", as recited in independent claims 217. For example, the American Heritage Dictionary of the English Language defines "crescent" as "the figure of the moon as it appears in its first or last quarter". The American Heritage Dictionary of the English Language, Fourth Edition (emphasis added). Similarly, for example, the Merriam-Webster Online Dictionary defines "crescent" as "the moon at any stage between new moon and first quarter and between last quarter and the succeeding new moon". Merriam-Webster Online Dictionary, 15 May 2008 (emphasis added). Because the Dove implant has a horseshoe shape that extends over 180 angular degrees, the Dove implant could not reasonably be construed as having "an elongate crescent-shaped outer cross-section", as recited in independent claim 217.

For at least the reasons set forth above, the Applicant submits that one of ordinary skill in the art would not be motivated to combine the structural features associated with the Dove implant with the Bianchi implant to arrive at the implant recited in independent claim 217, and that neither Bianchi nor Dove disclose each of the elements and features recited in independent claim 217. Accordingly, the Applicant submits that independent claim 217 is patentable over Bianchi and Dove and respectfully requests withdrawal of the rejection of independent claim 217 and allowance of the same.

Dependent claims 218-229 and 240-244 depend either directly or indirectly from independent base claim 217, and are submitted to be patentable for at least the reasons set

forth above in support of the patentability of independent base claim 230. However, further reasons support the patentability of dependent claims 218-229 and 240-244.

For example, claim 220 recites that "said first and second implants are positioned such that said longitudinal axis of said first implant lies at an oblique angle relative to said longitudinal axis of said second implant". As an initial matter, the Office Action does not set forth any grounds whatsoever as to how Dove or Bianchi satisfy the subject matter recited in claim 220. Accordingly, a *prima facia* case of obviousness has not been established with regard to claim 220. Furthermore, Dove discloses a single spinal implant, and not a pair of spinal implants positioned adjacent one another with concave outer surfaces defined by each of the implants facing one another to define a chamber therebetween, as recited in claim 220. With regard to Bianchi, although Figures 6, 8 and 9 illustrate a pair of implants positioned adjacent one another within an intervertebral disc space, the implants appear to extend along longitudinal axes arranged parallel to one another. As a result, Bianchi does not explicitly disclose that the longitudinal axis of the first implant lies "at an oblique angle" relative to the longitudinal axis of the second implant, as recited in dependent claim 220.

Additionally, claim 240 is directed to a method of forming the spinal implant of independent claim 217, and recites that steps of "providing a long bone having a diaphysis", "removing a cross-sectional bone slice from the diaphysis of the long bone . . . including an outer cortical bone wall surrounding an inner medullary canal having a length", and "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". As indicated above, Dove fails to disclose or suggest that the spinal implant is formed from bone. Additionally, as will be discussed in detail below with regard to independent claim 250, Bianchi does not explicitly disclose the recited combination of steps of "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". Claims 241-244 depend either directly or indirectly from claim 240, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 217 and intermediate claim 240.

New claims 263-270 have been added which recite various features associated with the insertion end of the implant. Support for new claims 263-270 is found, for example, at

page 18, line 27 to page 19, line 4, and in Figure 22 of the as-filed application. The Applicant further submits that that the features recited in new claims 263-270 are not disclosed in Dove or Bianchi, whether considered alone or in combination with one another.

Independent Claim 230 and Dependent Claims 231, 232, 234, 236-239, 245-249 and 271-276

Independent claim 230 has been rejected as being anticipated by Bianchi. Independent claim 230 has been amended and now recites, among other elements and features, an elongate bone portion including opposite first and second bone engaging surfaces "defining an implant height therebetween", "a first sidewall . . . defining a concave outer surface extending . . . from said first bone engaging surface to said second bone engaging surface" and "a second sidewall . . . including a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface and substantially entirely along said implant height", and "wherein said concave outer surface defined by said first sidewall is positioned opposite said substantially planar outer surface of said second sidewall relative to said longitudinal axis".

The features incorporated into independent claim 230 regarding the implant height being defined between first and second bone engaging surfaces is illustrated in Figure 2 of the as-filed application, with the implant height 21, 23 defined between the upper and lower bone engaging surfaces 40, 42, and with the substantially planar outer surface of the sidewall 16 extending substantially entirely along the implant height 21, 23 from the upper bone engaging surface 40 to the lower bone engaging surface 42.

The Office Action states that the implants illustrated in Figures 8, 13, 16 and 35 of Bianchi include each of the elements and features recited in independent claim 230. Specifically, the Office Action generally asserts that Bianchi discloses a "second sidewall extending between the first and second bone engaging surfaces and including a substantially planar outer surface (FIGS. 8, 13, 16 and 35) extending along the longitudinal axis between the first and second end portions from the first bone engaging surface to the second bone engaging surface; and wherein the concave outer surface defined by the sidewall is positioned opposite the substantially planar outer surface of the second sidewall relative to the longitudinal axis". (See page 4, lines 13-19). However, the Office Action fails to specify

which features associated with first and second sidewalls of the Bianchi implant comprise the "substantially planar outer surface" and the "concave outer surface . . . positioned opposite said substantially planar outer surface". Because the Office Action fails to set forth grounds with sufficient specificity and clarity to enable the Applicant to properly respond to the rejection of independent claim 230, the Office Action fails to establish a *prima facia* case of anticipation with regard to independent claim 230.

Nevertheless, in order to advance prosecution of the application, the Applicant has amended independent claim 230 to recite that the second sidewall includes "a substantially planar outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface and substantially entirely along said implant height", and with the concave outer surface defined by the first sidewall "positioned opposite said substantially planar outer surface" of the second sidewall. The Applicant submits that the specific combination of elements and features recited in independent claim 230 are not disclosed in Bianchi or any of the references of record, whether considered alone or in combination with one another. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 230 and allowance of the same.

Dependent claims 231, 232, 234 and 236-239 depend either directly or indirectly from independent base claim 230 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 230. However, further reasons support the patentability of dependent claims 231-239.

For example, claim 231 recites that the first sidewall includes "a first substantially planar outer surface adjacent said first end portion and a second substantially planar outer surface adjacent said second end portion", and "wherein said concave outer surface extends axially between said first and second substantially planar outer surfaces". Although the Office Action asserts that the Bianchi implant satisfies the features recited in claim 231, once again, the Office Action fails to specify which surfaces defined by a sidewall of the Bianchi implant constitute "a first substantially planar outer surface adjacent said first end portion" and "a second substantially planar outer surface adjacent said second end portion".

Accordingly, a *prima facia* case of anticipation has not been established with regard to claim 231.

Claim 245 is directed to a method of forming the spinal implant of independent claim 230, and recites that steps of "providing a long bone having a diaphysis", "removing a cross-sectional bone slice from the diaphysis of the long bone . . . including an outer cortical bone wall surrounding an inner medullary canal having a length", and "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". As indicated above, Dove fails to disclose or suggest that the spinal implant is formed from bone. Additionally, as will be discussed in detail below with regard to independent claim 250, Bianchi does not specifically disclose the recited combination of steps of "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". Claims 246-249 depend either directly or indirectly from claim 245, and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 230 and intermediate claim 245.

New claims 271-276 have been added which recite various features associated with the insertion end of the implant. Support for new claims 271-276 is found, for example, at page 12, line 30 to page 13, line 3; page 14, lines 17-24, and in Figures 1-3 and 5 of the as-filed application. The Applicant further submits that that the features recited in new claims 271-276 are not disclosed in Dove or Bianchi, whether considered along or in combination with one another.

Rewritten Independent Claim 233

The Applicant has rewritten dependent claim 233 in independent form. Rewritten independent claim 233 recites, among other elements and features, first and second bone engaging surfaces arranged generally opposite one another and that "each of said first and second bone engaging surfaces is substantially planar", "a first sidewall . . . including a recessed area . . . defining a concave outer surface extending . . . from said first substantially planar bone engaging surface to said second substantially planar bone engaging surface", and "a second sidewall arranged generally opposite said first sidewall . . . and including a substantially planar outer surface extending . . . from said first substantially planar bone engaging surface to said second substantially planar bone engaging surface".

As an initial matter, the Office Action fails to set fourth any grounds whatsoever as to how Bianchi satisfies the recitation that the first and second bone engaging surfaces are "substantially planar". Instead, the Office Action merely asserts that the Bianchi implant includes "a first bone engaging surface and a second bone engaging surface arranged generally opposite the first bone engaging surface". (See page 4, lines 5-7). Indeed, there is no discussion whatsoever as to how the bone engaging surfaces of Bianchi are "substantially planar". Therefore, a *prima facia* case of anticipation has not been established with regard to claim 233.

Furthermore, the Applicant submits that Bianchi does not disclose substantially planar bone engaging surfaces arranged generally opposite one another with "a concave outer surface extending . . . from said first substantially planar bone engaging surface to said second substantially planar bone engaging surface and "a substantially planar outer surface extending . . . from said first substantially planar bone engaging surface to said second substantially planar bone engaging surface", and with "said concave outer surface . . . positioned opposite said substantially planar outer surface . . . relative to said longitudinal axis", as recited in rewritten independent claim 233. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 233 and allowance of the same.

Rewritten Independent Claim 235

The Applicant has rewritten claim 235 in independent form. Rewritten independent claim 235 recites, among other elements and features, a first bone engaging surface, a second bone engaging surface arranged generally opposite the first bone engaging surface, and "said first and second bone engaging surfaces are separated by a first height adjacent said first end portion and by a second height adjacent said second end portion, wherein said first height is greater than the second height".

As an initial matter, the Office Action fails to set fourth any grounds whatsoever as to how Bianchi satisfies the recitation that "said first and second bone engaging surfaces are separated by a first height adjacent said first end portion and by a second height adjacent said second end portion, wherein said first height is greater than the second height". Instead, the Office Action merely asserts that the Bianchi implant includes "a first bone engaging surface and a second bone engaging surface arranged generally opposite the first bone engaging

surface", with no indication whatsoever as to how the Bianchi implant has a first height adjacent a first end portion that is greater than a second height adjacent an opposite second end portion. Therefore, a *prima facia* case of anticipation has not been established with regard to claim 235. Furthermore, the Applicant submits that Bianchi does not disclose each of the features recited in rewritten independent claim 235. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 235 and allowance of the same.

Independent Claim 250 and Dependent Claims 251-262

Independent claim 250 has been rejected as being anticipated by Bianchi. The entire grounds in support of the rejection of independent claim 250 is set forth on the top of page 5 of the Office Action where an assertion is made that "the method steps . . . would have been inherently carried out in the operation of the device". Applicant submits that independent claim 250 recites specific steps for forming a spinal implant. A single conclusory statement which merely asserts that multiple method steps would have been inherently carried out in the operation of a device does not establish a *prima facia* case of anticipation. Furthermore, as will be discussed in detail below, Bianchi does not specifically disclose each of the steps recited in independent claim 250.

In order for an element to be inherently disclosed, it must "necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson , 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). Furthermore, inherency "may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1951. Additionally, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original). It is respectfully submitted that each of the acts and features recited in independent claim 250 regarding the method of forming a spinal implant are not disclosed in Bianchi. Additionally, the Office Action does not provide any basis in fact and/or technical reasoning

supporting how Bianchi satisfies the acts and features recited in independent claim 250. Indeed, the brief statement set forth in the Office Action that "the method steps . . . would have been inherently carried out in the operation of the device" is merely conclusory. Accordingly, a *prima facie* case of anticipation has not been established with regard to independent claim 250 and the claims depending therefrom.

Furthermore, independent claim 250 is directed to a method of forming a spinal implant and recites the specific steps of "removing a cross-sectional bone slice from the diaphysis of the long bone, the cross-sectional bone slice including an outer cortical bone wall surrounding an inner medullary canal having a length", "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal", and "forming an elongate bone portion from one of the plurality of bone slice segments".

The conclusory assertion set forth in the Office Action that "the method steps . . . would have inherently been carried out in the operation of the device" is not supported by the Examiner. Figures 16 and 16A-16D of Bianchi disclose a method of obtaining bone plugs from the diaphysis of a long bone via cutting circular bone portions transversely across the bone at various locations off-center from the medullary canal. Varying the off-center distance from the medullary canal results in the formation of bone plugs having varying sidewall thicknesses T1-T4, with the diameter of the plug remaining unchanged. (See column 8, lines 12-26).

As should be readily apparent, the steps recited in independent 250 are not disclosed by Bianchi,. For example, independent method claim 250 recites "removing a cross-sectional bone slice from the diaphysis of the long bone" and "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". Even assuming arguendo that the bone plugs are formed by removing a cross-sectional bone slice from the diaphysis of the long bone, Bianchi fails to specifically disclose the act of "cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments". To the contrary, each of the bone plugs is used to form a single bone dowel, and the bone plugs are not cut along the length of the medullary canal, nor

are the bone plugs divided into a plurality of bone slice segments. Instead, each of the bone plugs remains intact to provide a single implant.

For at least the reasons set forth above, independent claim 250 is not anticipated by Bianchi. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 250 and allowance of the same.

Dependent claims 251-262 depend either directly or indirectly from independent base claim 250, and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 250. However, further reasons support the patentability of dependent claims 251-262.

For example, claim 252 recites that "the cutting of the bone slice along the length of the medullary canal comprises dividing the bone slice into three bone slice segments, with each of the three bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the inner medullary canal". Once again, Bianchi fails to disclose cutting the bone slice along the length of the medullary canal, much less "dividing the bone slice into three bone slice segments". To the contrary, Bianchi discloses that each of the bone plugs is used to form a single bone dowel.

Claim 256 recites that "each of the first and second bone engaging surfaces is substantially planar". As indicated above with regard to rewritten independent claim 233, the Office Action fails to set forth any grounds as to how Bianchi satisfies these recited features. Accordingly, a *prima facia* case of anticipation has not been established with regard to claim 256. Additionally, the Applicant submits that Bianchi fails to disclose each of the features recited in claim 256.

Claim 261 recites that "the first and second bone engaging surfaces are separated by a first height adjacent the first end portion and by a second height adjacent the second end portion, wherein the first height is greater than the second height". As indicated above with regard to rewritten independent claim 235, the Office Action fails to set forth any grounds as to how Bianchi satisfies these recited features. Accordingly, a *prima facia* case of anticipation has not been established with regard to claim 261. Additionally, the Applicant submits that Bianchi fails to disclose each of the features recited in claim 261.

CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 217-276. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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